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January 8, 2007

**BY CM/ECF AND HAND DELIVERY**
The Honorable Magistrate Mary Pat Thynge
United States District Court
844 North King Street
Wilmington, DE 19801

Re: *Glaxo Group Limited v. Teva Pharmaceuticals USA, Inc. and Teva Pharmacuetical Industries Limited*, Civil Action No. 04-171-***

Dear Magistrate Thynge:

This letter is submitted as the response of defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited (collectively "Teva") to the letter of December 1, 2006, submitted by plaintiff Glaxo Group Limited ("Glaxo"). Glaxo's letter was submitted under authority of Local Rule 7.1.2(c), presenting for consideration *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370 (Fed. Cir. 2006). As explained in this letter, the *Abraxis* decision may be helpful to the Court's claim construction analysis. The *Abraxis* decision, however, does not provide any guidance on whether Glaxo is entitled to any scope of equivalents in this case, nor does it provide any basis for relieving Glaxo of its burden of proof with respect to the doctrine of equivalents.

1. In *Abraxis*, The Federal Circuit Rejected The District Court's Broad Construction Because It Was Not Supported By The Patent Specification.

The *Abraxis* decision is focused on the district court's construction of the term "edetate," ("EDTA") a preservative used in the patented formulation to retard microbial contamination of the formulation as it moves through the tubes and bags needed to deliver the active ingredient (an anesthetic) to patients during surgery. *Abraxis*, 467 F.3d at 1373 (describing the tubes and bags as a "giving set"). The patent at issue claimed "an amount of edetate sufficient to prevent a no more than 10-fold increase in growth" of various microbes in the formulation. 467 F.3d at 1375. In the specification, the patentee stated that: "By the term 'edetate' we mean ethylenediaminetetraacetic acid (EDTA) and derivatives thereof ...." *Id.* at 1376. The district court's construction, focusing on the terms "derivatives thereof" and relying upon an extrinsic expert declaration, defined "edetate" to mean "EDTA as well as compounds structurally related to EDTA regardless of how they are synthesized." *Id.* at 1375.

The Federal Circuit reversed the district court's construction, finding the inclusion of "compounds structurally related to EDTA" to be impermissibly broad, given the context of the entire specification, which listed various EDTA salts, but did not include "structural analogs" of EDTA. *Id* at 1377. The *Abraxis* court also observed that the specification disclosed considerable efforts expended by the patentee to test other known preservatives, all of which did not solve the microbial contamination problem addressed by the claimed invention. *Id.* The patentee noted, to its surprise, that edetate "was the *only* agent that would meet our requirements." *Id.* (emphasis in original). The Federal Circuit thus reversed the district court's broad construction, holding the proper construction of "edetate" to be "EDTA and derivatives of EDTA, such as salts, but not including structural analogs." *Id* at 1378.

In this case, the specification of the '249 patent does not attempt to define "ethanol" in any manner, and does not list or suggest that any excipient but ethanol is within the scope of the described invention. (Teva Br. In Supp. of its Claim Const. D.I. No. 101, at pp. 3-4). Further, throughout the prosecution of the '249 patent, similar to the specification on *Abraxis*, Glaxo emphasized that "only by the present invention," would one of ordinary skill in the art recognize the stabilizing benefits of ethanol in the formulation. (DI. No. 107, Ex. 3, p. G000206)(emphasis added)). Under *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed Cir. 2005), the prosecution history is

useful intrinsic evidence for demonstrating how the inventor understood the invention at issue. *Phillips*, 415 F.3d at 1317.

In *Abraxis*, the claim scope was limited by the specific examples of the excipient at issue that were disclosed in the specification. This Court, like the *Abraxis* court, should similarly limit Glaxo's '249 patent scope to ethanol, and ethanol alone.

2. The *Abraxis* Decision Is Not Relevant To Whether Glaxo's Patent, As A Matter Of Law, Is Entitled To Any Scope Of Equivalents.

As it pertains to the doctrine of equivalents, Glaxo's letter stretches the *Abraxis* holding beyond its fair scope in an attempt to characterize and re-argue whether any scope of equivalents is available as a matter of law to Glaxo in this case. There is no mention in *Abraxis* of any amendments to the scope of the claims at issue during prosecution. That happened in this case. (See Teva Reply Br. In Supp. Mot. For Summary Judgment of Non-Infringement, D.I. No. 150, at pp. 10-15.) There is no mention in *Abraxis* of a declaration submitted by the patentee to the Patent Office with the results of experiments conducted to show the Patent Office what a "substantial enhancement" in stability means. That happened in this case. (See Teva's Opening Br. In Supp. Of Its Claim Construction, D.I. No. 101, at pp. 11-14.) There is no mention in *Abraxis* of the patentee actually experimenting with the accused excipient before the application was filed and rejecting the very compound it now claims is the equivalent of ethanol. That also happened in this case. (See Teva Reply Br., D.I. No. 150, at p.3.) On this basis alone, the *Abraxis* decision is not factually relevant to whether Glaxo is entitled to any scope of equivalence as a matter of law in this case.

Contrary to Glaxo's summary, Teva's "public policy" arguments go far beyond the simple proposition that narrow claims alone justify the preclusion of any scope of equivalency in this case. Without arguing the merits again in this letter, Teva simply reminds the Court that the facts set forth in *Tanabe Seiyaku Co. v. United States International Trade Commission*, 109 F.3d 726 (Fed. Cir. 1997) are much more aligned with the facts in this case than with the facts in the *Abraxis* decision. Further, rather than restate the same legal reasons why Glaxo cannot expand the scope of "ethanol" to include propylene glycol, Teva respectfully refers the Court to its Opening and Reply Briefs in support of its Motion for Summary Judgment of Non-Infringement (D.I. Nos. 104 and 150).

3. The *Abraxis* Decision Emphasizes That Genuine Issues Of Material Fact Preclude Summary Judgment Against Teva In This Case.

Because the facts underlying the finding of infringement in *Abraxis* are unique to the *Abraxis* patent and the accused formulation, Glaxo's reliance upon *Abraxis* to relieve Glaxo of its burden of proof against Teva is misplaced. As recognized by the Supreme Court since 1950, "[a] finding of equivalence is a determination of fact," predicated on the "balancing of credibility, persuasiveness and weight of evidence." *Graver Tank v. Linde Air*, 339 U.S. 605, 609-610 (1950). The *Abraxis* opinion reiterates this long-held principle, stating that "[w]hat constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case." *Abraxis*, 467 F.3d at 1380 (quoting *Graver Tank v. Linde Air*, 339 U.S. 605, 609 (1950)).

Moreover, the district court in *Abraxis* had the benefit of an eleven-day bench trial before it made its determination of equivalents. 467 F.3d at 1374. The parties in *Abraxis* also had the benefit of the district court's claim construction during the eleven-day bench trial. *Id.* No doubt, such a record afforded the district court, as the finder of fact, ample foundation "to determine the weight and credibility of the evidence" proffered by both parties. *AstraZeneca v. Mayne Pharm (USA) Inc.*, No. 02 Civ. 7936, 2005 WL 2864666 at * 1 (S.D.N.Y. 2004 Nov. 2, 2005). There is no such record here.

To the contrary, Glaxo has presented nothing in this case but the conclusory opinion of its expert, which did not compare the stability of Teva's accused formulation with propylene glycol to the stability of the same formulation without propylene glycol. This fundamental lack of proof is not cured by Glaxo's tenuous effort to draw analogies between the proof presented by the patentee in the *Abraxis* trial and the summary judgment briefing presently before the Court.

Moreover, even if the Court believes that Glaxo has shown "that propylene glycol enhances the stability of ranitidine in the same way as ethanol by inhibiting the hydrolysis and/or oxidation of ranitidine in an aqueous formulation for oral administration," this still cannot be the basis for a grant of summary judgment against Teva on equivalents. Glaxo's own expert has identified three functions that ethanol serves in a ranitidine solution. There are fact issues precluding judgment as a matter of law as to whether Glaxo has proven the propylene glycol in Teva's formulation performs even one of those functions, let alone all three. Indeed, Glaxo's

failure to prove that propylene glycol performs all three of the functions served by ethanol in Glaxo's patent is ample reason to grant Teva's motion for summary judgment of non-infringement.

Teva respectfully submits, on the basis of the evidence and the briefs before the Court (which Teva will not again repeat) that summary judgment finding infringement under the doctrine of equivalents as a matter of law is not proper here. Rather, as a matter of law, Glaxo is not entitled to expand the scope of its patent to include propylene glycol by means of the doctrine of equivalents. Moreover, as a factual matter, Glaxo has failed to prove that Teva's propylene glycol performs all three functions that ethanol performs in its patent. Summary judgment of non-infringement in favor of Teva is, therefore, appropriate here.

Respectfully submitted,

Karen E. Keller (No. 4489)

cc: All Counsel